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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/738,455	12/16/2003	Timothy J. Jegla	018512-001420US	9589
20350 7590 06/12/2007 TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			EXAMINER SEHARASEYON, JEGATHEESAN	
			ART UNIT 1647	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/738,455

**Applicant(s)**

JEGLA, TIMOTHY J.

**Examiner**

Jegatheesan Seharaseyon, Ph.D

**Art Unit**

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 11 and 14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11 and 14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### ***Status of Application, Amendments and/or Claims***

1. This Office Action is in response to Applicant's remarks and amendments filed 3/26/2007 have been entered in full. Claims 11, 14, 15 and 36 were pending. Applicant has cancelled claims 15 and 36. Applicant has also amended claims 11 and 14.

2. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

3. Any objection or rejection of record, which is not expressly repeated in this action, has been overcome by Applicant's response and withdrawn.

4. the Office acknowledges the receipt of the correction for the specification.

### ***Claim Rejections - 35 USC § 112, first paragraph, (written description) maintained***

5. The rejection of claim 14 under 35 USC § 112, first paragraph, as lacking written description support is maintained for reasons set forth in the Office Action mailed 1/12/2007 (see pages 5-7).

The specification discloses a protein of SEQ ID NO: 17 and a nucleic acid sequence of SEQ ID NO: 18 that encodes the protein of SEQ ID NO: 17. However, claim 11 is drawn to a polypeptide having greater than 90% sequence identity to SEQ ID NO: 17 having the ability to form with at least one additional voltage-gated potassium channel (Kv) alpha subunit, a heteromeric potassium channel having the characteristic of voltage gating. The claims do not require that the proteins possess any particular biological activity, other than polypeptide monomer form a potassium channel having

Art Unit: 1647

the characteristic of voltage gating, nor any particular conserved structure, or other disclosed distinguishing feature. Thus, the claims are drawn to a genus of polypeptide molecules.

Applicant's arguments (3/26/2007) as they pertain to the rejections have been fully considered but are not deemed to be persuasive for the following reasons. It is noted that at pages 7-8 of the Response, Applicant cites pertinent case law reviewing the legal standard of written description. The Examiner takes no issue with Applicant's general comments regarding the legal standard for written description.

Applicant's argue at page 8 of the response that the pending claims set forth both functional features, e.g., polypeptide comprising a subunit of a voltage-gated potassium channel (Kv alpha subunit), and structural features, e.g., a polypeptide having at least 90% sequence identity to SEQ ID NO: 17. Applicant argues at page 10 of the response that voltage-gated potassium channels have well-defined structures (such as the conserved S4-S6 transmembrane domain as well as "subunit association" region) and the functionality of these variants can be readily verified by methods well known in the art or taught in the specification.

Applicant's arguments (filed 3/26/2007) have been fully considered but are not persuasive for the following reasons. Applicant has not described or shown possession of all polypeptides that share 90% sequence similarity to SEQ ID NO: 17 and still retain the function of SEQ ID NO: 17 or that is capable of forming a heteromeric potassium channel. Nor has Applicant described a representative number of species that have 90% homology to SEQ ID NO: 17, such that it is clear that they were in possession of a

Art Unit: 1647

genus of polypeptides functionally similar to SEQ ID NO: 17. Furthermore, the broad brush discussion of making and screening for variants in the instant specification does not constitute a disclosure of a representative number of members. No such variants were made or shown to have activity. Only the Kv alpha subunit polypeptide of SEQ ID NO: 17 is disclosed. The specification's general discussion of making and screening for variants constitutes an invitation to experiment by trial and error. Such does not constitute an adequate written description for the claimed variants. One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. To provide evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, and any combination thereof. In this case, the only factor present in the claims is a partial structure in the form of a recitation of percent identity. Although Applicant argues that the pending claims recite a functional limitation, i.e., polypeptide is a subunit of a potassium channel forming a heteromeric K channel having the characteristic of voltage gating (this is not a function but a characteristic of the protein), the claims do not require that the proteins encoded possess any particular biological activity. While the disclosure provides general guidance on the conserved features of voltage-gated potassium channels in general, the disclosure has not shown which features of the protein of SEQ ID NO: 17 are critical to its specific activity. Moreover, as discussed in the 101 rejection below, there have been 19 functional Kv  $\alpha$ -subunits and

Art Unit: 1647

10 silent (i.e., regulatory) subunits that have been discovered thus far, and that despite the large number of these subunits, their exact physiological role is still poorly understood. Therefore, while the Applicant argues that the pending claims recite a functional limitation, i.e., a subunit of a voltage-gated potassium channel having the characteristic of voltage gating, the fact that there are an exceedingly large number of these subunits with differing functions supports the Examiner's position that the claims do not require that the proteins possess any particular biological activity. While the disclosure provides general guidance on the conserved features of voltage-gated potassium channels in general, there are at least 29 different voltage-gated potassium channel subunits with differing function, and the disclosure has not shown which features of the protein encoded by the nucleic acid of SEQ ID NO:17 are critical to its specific activity. Accordingly, the distinguishing characteristics of the claimed genus are not described. The only adequately described species is the polypeptide of SEQ ID NO: 17. Accordingly, such does not constitute disclosure of a representative number of examples of, nor adequate written description for, the claimed genus.

*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

With the exception of the polypeptide sequence referred to above, the skilled artisan cannot envision the detailed chemical structure of the encompassed polypeptides molecules, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only the polypeptide of SEQ ID NO:17, but not the full breadth of the claims meet the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

***Claim Rejections - 35 USC § 112, 1<sup>st</sup> Paragraph (Scope of Enablement),  
maintained***

6. The rejection of claim 14 under 35 USC § 112, first paragraph, as lacking in scope of enablement is maintained for reasons set forth in the Office Action mailed 1/12/2007 (see pages 7-10).

Claim 11 is drawn to an isolated polypeptide comprising an alpha subunit of a

Art Unit: 1647

heteromeric voltage-gated potassium channel, wherein the subunit has greater than 90% sequence identity to SEQ ID NO: 17, having the ability to form with at least one additional voltage-gated potassium channel (Kv) alpha subunit, a heteromeric potassium channel having the characteristic of voltage gating. The claims do not require that the proteins possess any particular biological activity, other than encoding a subunit of a potassium channel having the characteristic of voltage gating, nor any particular conserved structure, or other disclosed distinguishing feature. Thus, the disclosure fails to provide sufficient guidance and information regarding the structural and functional requirements commensurate in scope with what is encompassed by the instant claims.

Applicant's arguments (3/26/2007) as they pertain to the rejections have been fully considered but are not deemed to be persuasive for the following reasons. Applicant argues at page 12 of the response that voltage-gated potassium channels have well-defined structures and readily testable functional features. In addition, Applicant argues at pages 13-14 of the response that the specification contains assays for testing the function of the variant Kv channels. Applicant argues at pages 12-14 of the response that upon reading the specification, a skilled artisan would recognize portions of SEQ ID NO: 17 that are important to its function as a voltage-gated potassium channel subunit, thus directing the skilled artisan in choosing the locations and/or nature of possible sequence modifications.

Applicant's arguments (filed 3/26/2007) have been fully considered but are not persuasive for the following reasons. The specification's disclosure is insufficient to



Art Unit: 1647

enable one skilled in the art to practice the invention as broadly claimed without undue experimentation. The factors listed below have been considered in the analysis of enablement:

- (A) The breadth of the claims;
- (B) The nature of the invention;
- (C) The state of the prior art;
- (D) The level of one of ordinary skill;
- (E) The level of predictability in the art;
- (F) The amount of direction provided by the inventor;
- (G) The existence of working examples; and
- (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The claims are drawn to a genus of polypeptide having greater than 90% sequence identity to SEQ ID NO: 17. However, the specification does not provide any evidence which identifies the particular subfamily of voltage-gated potassium channel to which this subunit belongs. While the Applicant argues that the pending claims recite a functional limitation, i.e., a subunit of a voltage-gated potassium channel or an alpha subunit of a heteromultimer voltage-gated potassium channel, the claims do not require that the proteins possess any particular biological activity. Moreover, while the disclosure provides general guidance on the conserved features of voltage-gated potassium channels, neither the disclosure has not shown (1) which portions of the protein of SEQ ID NO: 17 are critical to the activity of the protein of SEQ ID NO:17 (which is itself unknown); (2) what modifications e.g., substitutions, deletions, or additions) one can make to SEQ ID NO:17 that will result in protein mutants or variants with the same function/activity as the protein of SEQ ID NO:17; (3) any guidance on how to use the variants of SEQ ID NO:17 which would, based on the language of said

Art Unit: 1647

claims, encompass both active and inactive variants, especially in the absence of any functional limitations in the claims; and (4) what modifications e.g., substitutions, deletions, or additions) one can make to SEQ ID NO:17 that will result in a polypeptide having greater than 90% sequence identity to SEQ ID NO:17 and forms a heteromultimeric potassium channel.

As stated at pages 9-10 of the previous Office action, The state of the art is such that the relationship between the sequence of a protein and its activity is not well understood and is unpredictable, and that certain positions in the sequence are critical to the protein's structure/function relationship and can only tolerate only relatively conservative substitutions or no substitutions. While the disclosure provides general guidance on the conserved features of voltage-gated potassium channels in general, the disclosure has not shown which features of the protein of SEQ ID NO: 17 are critical to its specific activity, nor would they be readily apparent to the skilled artisan based on the disclosure at the time the application was filed. A large quantity of experimentation would be required by the skilled artisan to generate the infinite number of derivatives recited in the claims and screen the same for activity. Furthermore, the broad brush discussion of making and screening for variants in the instant specification constitutes an invitation to experiment by trial and error. As was found in Ex parte Hitzeman, 9 USPQ2d 1821 (BPAI 1987), a single embodiment may provide broad enablement in cases involving predictable factors such as mechanical or electrical elements, but more will be required in cases that involve unpredictable factors such as most chemical reactions and physiological activity. See also In re Fisher, 427 F.2d 833, 839, 166

Art Unit: 1647

USPQ 18, 24 (CCPA 1970); Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 927 F.2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed. Cir.), cert. denied, 502 U.S. 856 (1991).

Proper analysis of the Wands factors was provided in the previous Office Action. Due to the large quantity of experimentation necessary to generate the infinite number of derivatives recited in the claims and possibly screen the same for activity, the lack of direction/guidance presented in the specification regarding which structural features are required in order to provide activity the absence of working examples directed to same; the complex nature of the invention; the state of the prior art which establishes the unpredictability of the effects of mutation on protein structure and function; and the breadth of the claims which fail to recite any structural limitations, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

***Claim Rejections - 35 USC § 101 and 35 USC §112, 1<sup>st</sup> Paragraph (New)***

7. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11 and 14 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility. Novel biological molecules lack an established utility and must undergo extensive experimentation to determine an appropriate specific and substantial utility.

The instant application discloses polypeptide of SEQ ID NO: 17 (Kv6.2). The specification asserts that, this polypeptide monomer is a member of the "Kv" superfamily of potassium channel monomers. Members of this family are polypeptide monomers that are subunits of voltage-gated potassium channels having six transmembrane regions (K=potassium, v=voltage-gated). Voltage-gated potassium channels have significant roles in maintaining the resting potential and in controlling excitability of a cell (See page 8, lines 17-27).

The specification discloses that when human Kv6.2 monomer is co-expressed in *Xenopus* oocytes with human Kv2.1 monomer it produces voltage gated current (page 63). However, the specification does not provide an expression profile (for example: where it is expressed) of this gene or protein. Although the specification contemplates the use of Kv6.2 in CNS related diseases (see page 12), the prior art published after the priority date discloses that the Kv6.2 mRNA is preferentially expressed in myocardium (Zhu et al. *Receptors and Channels* 6(5): 337-350, 1999, Ref AJ of PTO1449 filed 12/16/2003). In addition, the instant specification does not teach any physiologic ligands or modulators of the Kv6.2 polypeptide set forth in SEQ ID NO: 17. There is no well-established utility for a specific amino acids of Kv6.2, and the specification fails to

disclose a specific and substantial utility for the claimed invention. The instant application does not disclose a specific biological role for the Kv6.2 protein or its significance to a particular disease, disorder, or physiological process which one would manipulate for a desired physiological or clinical effect.

Based on sequence homology and the co expression, the specification asserts the following as patentable utilities for the claimed Kv6.2 polypeptides:

- 1.) assaying for inhibitors and activators of heteromeric voltage-gated potassium channel (page 11, lines 29-30);
- 2.) studying channel kinetics (page 12, lines 5-6,);
- 3.) pharmaceutical agents for treating diseases, including CNS diseases (page 12, line 8);
- 4.) diagnostic applications (page 12, lines 9-10);
- 5.) chromosomal localization to identify diseases (page 12, lines 11-12);
- 6.) computer assisted drug design (page 49);
- 7.) gene therapy (page 52).

These asserted utilities are neither specific nor substantial because they do not identify or reasonably confirm a "real world" context of use. The specification neither identifies the biological functions of the Kv6.2 proteins, nor any diseases that are associated with the claimed molecules. Without any biological activity or link to a disease, such constitutes further research to determine the properties of the claimed Kv6.2 proteins of SEQ ID NO: 17 the specification lacks support to meet the requirement of 35 USC § 101.

Although the Kv6.2 of SEQ ID NO: 17 is a subunit of a voltage-gated potassium channel, their identification as such is not sufficient to establish either a well-known, or a specific and substantial utility. The art teaches that voltage-gated potassium channels serve a wide range of functions, including regulation of the resting membrane potential, and control of the shape, duration, and frequency of action potentials. The art also teaches that there is a great diversity of voltage-gated  $K^+$  channels in neuronal and muscular cells which have different biophysical, regulational, and pharmacological properties (Hugnot et al. EMBO J. 15(13):3322-3331, 1996). These voltage-gated potassium channels are composed of four homologous  $\alpha$ -subunits, and the functional variability of the  $K^+$  currents arises from several mechanisms, including the ability of  $\alpha$ -subunits within a family to aggregate into oligomers, regulatory hydrophilic  $\beta$ -subunits that can coassemble with  $\alpha$ -subunits, as well as regulatory  $\alpha$ -subunits (Castellano et al. J. Neurosci. 17(12): 4652-4661, 1997). The art also teaches that thus far, 19 functional Kv  $\alpha$ -subunits and 10 silent (i.e., regulatory) subunits have been discovered, and that despite the large number of these subunits, their exact physiological role is still poorly understood mainly because of the difficulty in recognizing a silent subunit in isolated cells or in tissue (Ottschytsch et al. Proc. Natl. Acad. Sci. USA. 99(12): 7986-7991, 2002, Ref AI of PTO1449 filed 12/16/2003). Ottschytsch et al. also teach that heterologous expression studies have led to the hypothesis that the silent subunits must interact with other Kv subunits from the Kv2 and Kv3 subfamilies to regulate their function, and if each of the silent subunits discovered thus far can interact with the two members of the Kv2 subfamily and the four members of the Kv3 subfamily, then at least

Art Unit: 1647

60 different heterotetramers are possible. They conclude by stating that this growing group of silent subunits considerably expands the potential for molecular diversity of the native K<sup>+</sup> channels and that future experiments will be necessary to reveal the true interaction partners and the physiological importance of the silent subunits (See page 7991, right column).

Although the conserved K<sup>+</sup> selective pore region and S4-S6 domains allows identification of such as a voltage-gated potassium channel subunit, mere homology and co expression studies are not accepted by those of skill in the art as being predictive of function, especially given the great diversity of voltage-gated potassium channels discussed *supra*. Utility must be in readily available form. It is possible that, after further characterization, this protein might be found to have a patentable utility, in which case proteins would have a specific utility, or the protein might be found to be associated with a specific disease or disorder. This further characterization, however, is part of the act of the invention, and until it has been undertaken, Applicant's claimed invention is incomplete. Furthermore, whereas one could readily employ the Kv6.2 of SEQ ID NO: 17 of the instant invention in an assay to identify modulators thereof, the information obtained from such assays would be of little use until one discovers the identity of those physiological processes moderated by those proteins. Because the instant specification has failed to identify a physiological process which has been shown to be influenced by the activation or inhibition of the putative potassium channel proteins of the instant invention, an artisan would have no way of predicting what effects the administration of that modulator to an organism would have. If one cannot predict the

Art Unit: 1647

effects that the administration of a modulator of the potassium channel of the instant invention is going to have on an organism, then it is unclear as to what practical or real world benefit is derived by the public from the identification of that modulator.

It is possible that, after further characterization, the Kv6.2 protein may be found to have a specific and substantial credible utility. This further characterization, however, is part of the act of invention, and until it has been undertaken, Applicant's claimed invention is incomplete. The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sup. Ct, 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. §101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. The court held that:

"The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion."



In the Instant case, the instant specification leaves it to the practitioner to discover the identity of a disease or disorder in which the protein the instant invention is mutated or aberrantly expressed, and to discover the nature of that aberrant expression (i.e., overexpression or underexpression). The evidence of mere identification as a voltage-gated potassium channel based on sequence homology and co expression studies is not tantamount to a showing of a role of the polypeptide of SEQ ID NO: 17 in a disease/disorder, or that compounds that modulate its activity are useful in the treatment of a disease or disorder. Therefore, the claimed protein cannot be used in a therapeutic capacity without the need for a substantial inventive contribution. Such additional experimentation, if needed to identify a specific utility for an invention, is precluded by the court.

8. Claims 11 and 14 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to make/use the claimed invention.

9. No Claims are allowable.

#### **Contact Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon, Ph.D whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-5:00.

Art Unit: 1647

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, Ph. D can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JS  
Art Unit 1647  
June 8, 2007

*Gesamte Handwritten Signature*  
*Pat. Exam.*